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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,953	09/10/2003	Alexander Karl Huwig	20959/2140 (P 63469)	3518
7590 Nixon Peabody LLP Clinton Square P.O. Box 31051 Rochester, NY 14603-1051				
EXAMINER				
FUBARA, BLESSING M				
ART UNIT		PAPER NUMBER		
1618				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/658,953

Applicant(s)

HUWIG ET AL.

Examiner

BLESSING M. FUBARA

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-15, 17-27, 29 and 30 is/are pending in the application.
- 4a) Of the above claim(s) 5-10, 13 and 21-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 11, 12, 14, 17-20, 27, 29 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The examiner acknowledges receipt of request for extension of time, amendment and remarks filed 11/10/08. Claim 1 is amended. New claims 29 and 30 are added. Claims 1, 2 and 4-15, 17-27, 29 and 30 are pending. Claims 5-10,13 and 21-26 are withdrawn from consideration; claims 1, 2, 4, 11, 12, 14, 15, 17-20, 27 and new claims 29 and 30 are examined.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 2, 4, 11, 12, 14, 15, 17-20 and 27 remain rejected and new claim 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for reasons of record and reiterated herein. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

Claim 1 as amended recite a pH range of 1-3. Page 21, lines 23-25 envisions a pH range of 1-4, 1.5-3.5 and 2-3. Original claims 16 and 18 did not describe the now recited pH range.

Thus the specification as filed does not envision a pH range of 1-3. New claim 30 recites a pH of 3 while pH ranges of 1-4, 1.5-3.5 and 2-3 are disclosed/envisioned.

Applicant may overcome the rejection by removing the new matter from the claims

Response to Arguments

3. Applicant's arguments filed 11/10/2008 have been fully considered but they are not persuasive. Applicant argues that page 21, lines 23-25 "recites various pH ranges which establish multiple pH data points" of 1, 1.5, 2, 3, 3.5 and 4. But page 21, lines 23-25 discloses that "the pH value of the compositions according to the invention is preferably in the range of 1 to 4, particularly preferably 1.5 to 3.5 and quite particularly preferably 2 to 3," and it is clear that none of the ranges disclosed is 1-3 and no specific pH aside from the ranges is disclosed.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 2, 4, 11, 12, 14, 15, 17-20 and 27 remain rejected and new claims 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hughes et al. (US 6,004,538) in view of Asano et al. (US 4,568,540) for reasons of record and reiterated herein below with modification to address new claims 29 and 30.

Hughes discloses liquid dentrifice and mouthwash compositions that comprise one or more of oral composition components that are selected from abrasives, binders such as xanthan gum and carboxymethylcellulose at 0.1-5%, humectants, surfactants, fluoride ion sources, anticalculus agents and sweeteners and additionally comprises dimethicone copolyol selected from alkyl- and alkoxy-dimethicone copolyols (abstract; column 5, lines 30-35, 52-65); may also include lipophilic flavorants and lipophilic antimicrobial compounds (column 4, lines 29-62). Silica gels or xerogels (column 6, line 10) or calcium carbonate (column 6, lines 22 and 23) are abrasive agents. The composition of Hughes may also contain surfactants (column 6, lines 34-48), soluble fluoride ions such as sodium fluoride, stannous fluoride (column 6, lines 49-55), anti-calculus agents, of which specific example is zinc compounds (column 6, line 59 to column 7 line 22), sweetening and flavoring agents at 0.005 to about 2% and humectants (column 7, lines 23-26, 43), bleaching agent (column 7, line 52 to column 8, line 45), optional agents such as dyes/colorant, pH adjusting agents, plant extracts and desensitizing agents such as potassium nitrate, and mixtures thereof (column 7, lines 27-41), and effervescent agents such as carbonate that are effective under acidic conditions and mixed with organic acids such as citric acid, malic

acid, succinic acid and gluconic acid (column 8, lines 13-23). The composition may also contain polyethylene glycols (column 10, lines 60 and 61) and phosphonic acid chelating agents at 0.1-1% (column 12, line 16); and the composition contains from about 0-60% or 5-30% ethanol when it is a mouthwash (column 7, line 45) meeting claim 20. The xanthan gum and polyethylene glycol meet the limitation of polymer in claims 1 and 12. The presence of phosphonic acid, citric acid meets the acid requirements of claims 1, 4 and 11. The fluoride ions meet the requirements of claim 14; potassium nitrate is a source of potassium ion meeting claim 15; carboxymethylcellulose meets the film-forming agent of claim 1; the sweetening agent at 0.005 to about 2% meets claim 19. Applying the composition containing desensitizing agent meets claim 27 and the composition of Hughes meets claim 18. The solubility of the acid recited in claim 2 is a property of the acid so that the acid of Hughes would have those properties and thus meet claim 2. Regarding claim 17, one film-forming agent may replace another without negatively affecting the composition. In this hydroxypropyl cellulose could be substituted for carboxymethyl cellulose with the expectation that the composition would be effective as a dentrifice.

Hughes discloses the claimed composition as described above. The difference between the Hughes composition and the claimed composition is that while Hughes teaches that the composition can be acidic, Hughes does not specifically teach a pH of from 1-4. However, Asano describes dentrifice composition containing fluoride ion from potassium of sodium fluoride at 0.0025 to 4%, zinc ions, polyethylene glycol, hydroxyl ethyl cellulose, silica abrasive, xanthan gum or carrageenan at 0.2 to 5%, humectants, succinic acid or gluconic acid or maleic acid or fumaric acid as buffering agents; 0.01 to 2% flavoring agent/sweetening; ethanol/water

solvent; Asano specifically teaches that the pH of the composition should be maintained at acidic pH of 3.5 to 6 in order to permit the fluoride to remain in solution instead of precipitating (abstract; column 2, line 39- 55; column 3, lines 7-59, column 4, lines 2, 11-14, 17-37; column 5, lines 30-43; Example 8 and claims 1-11). For claims 29 and 30, the artisan has the skills to adjust the pH of the composition to a value in which the fluoride ions are maintained in solution. Thus, when Hughes in view of Asano are taken together, the ordinary skilled artisan would have been motivated to maintain the pH of the composition at acidic pH of from 3.5 to 6 with the expectation of maintaining the fluoride and zinc ions in solution.

Response to Arguments

7. Applicant's arguments filed 11/10/08 have been fully considered but they are not persuasive.

Applicant argues that Asano does not disclose or suggest compositions including non-polymeric acid and composition having a pH of 1-3 and that the composition of Asano has pH of 3.5-6.0 as disclosed in column 3, lines 17-19. The examiner agrees with applicant that the Asano indicates that the pH of the composition should be maintained at 3.5 to 6.0 and it is because the pH of the composition is not at 3 that the rejection is made under 35 USC 103. Further, it is noted that the Asano specifically says that the pH should be adjusted and the pH range taught Asano indicates a variable pH adjustable to achieve desired composition for effective oral care. Secondly, a pH of 3.5 renders a pH of 3 keeping in mind that pH range of 1-3 is claimed indicating that the pH is variable. There is no demonstration that the recited pH range of 1-3 provides unexpected results.

Regarding applicant's argument that Asano does not teach composition containing non-polymeric acid, it is noted that Asano is a secondary reference use to show that compositions containing fluoride ions are maintained at pH's in which the fluoride ions are in solution. Hughes, which is the primary reference, teaches compositions that contain phosphonic acid (column 12, line 16) and the phosphonic acid meets the limitation of the non-polymeric acid of claims 1, 4 and 11 and 18. Applicant's argument is centered around discrediting the secondary reference of Asano when the rejection is made over combination of references and one cannot show non-obviousness by attacking individual references.

Applicant also argues that Hughes uses acid in combination with effervescence generators, but, the comprising language of the claims is open and does not exclude effervescence generators.

Applicant argues that the examiner used hind sight in combining Hughes with Asano because a skilled artisan would not have any incentive of combining the "components in present claim 1." The examiner disagrees. The components of claim 1 were not combined to arrive at the claim 1. No hind sight reconstruction was made by the examiner because the skilled artisan would look to the suggestion of Asano to adjust pH of the composition of Hughes in order to maintain the fluorides ions in solution. Applicant says that Examples VI to VIII do not contain fluoride ions, but it is settled that a reference is not limited to its working examples, but must be evaluated for what it teaches (see *in re Boe*, 148 USPQ 507 (CCPA 1996) and *in re Chapman*, 148 USPQ 711 (CCPA 1966)). In the present case, Hughes contemplates compositions containing surfactants (column 6, lines 34-48), soluble fluoride ions such as sodium fluoride, stannous fluoride (column 6, lines 49-55).

No claim is allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Blessing M. Fubara/
Examiner, Art Unit 1618